

EXHIBIT 4

May 23, 2003

Arthur-Jean Williams
Chief, Environmental Field Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, 7506-C
Washington, D.C. 20460

May 23, 2003

Dear Ms. Williams:

This letter acknowledges the National Marine Fisheries Service's (NOAA Fisheries) receipt of the letter dated December 29, 2003, from the U.S. Environmental Protection Agency (EPA) requesting initiation of formal section 7 consultation under the Endangered Species Act (ESA). The action submitted for consultation is the re- registration of the pesticide products with the active ingredient diazinon under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA has requested consultation on the effects of this action on Pacific salmon in the following 26 salmonid Evolutionarily Significant Units (ESUs): Southern California steelhead, South-Central California Coast steelhead, Central California coast steelhead, California Central Valley steelhead, Northern California steelhead, Upper Columbia River steelhead, Snake River Basin steelhead, Upper Willamette River steelhead, Lower Columbia River steelhead, Middle Columbia River steelhead (*Oncorhynchus mykiss*); Sacramento River winter-run chinook, Snake River fall-run chinook, Snake River spring/summer-run chinook, Central Valley spring-run chinook, California Coastal chinook, Puget Sound chinook, Lower Columbia River chinook, Upper Willamette River chinook, Upper Columbia River spring-run chinook (*O. tshawytscha*); Central California coast coho, Southern Oregon/Northern California coast coho, Oregon coast coho (*O. kisutch*); Hood Canal summer-run chum, Columbia River chum (*O. keta*); Ozette Lake sockeye, and Snake River sockeye (*O. nerka*).

NOAA Fisheries has reviewed the initiation package entitled *Diazinon Analysis of Risks to Endangered and Threatened Salmon and Steelhead* (November 29, 2002). Before initiating formal consultation, NOAA Fisheries requests that EPA supplement its initiation packages with additional information. The information sought is described in Attachment 4 to this letter. Please respond by providing the information requested, or in the alternate, an explanation as to why the information sought is either unavailable or inappropriate. After NOAA Fisheries determines that EPA's initiation packages are complete, formal consultation will begin. We will notify you by letter when formal consultation has commenced, together with an estimate as to when we will complete consultation and provide you with a biological opinion.

To assist you in supplementing your initiation packages, we are enclosing two additional documents. While these documents have been provided previously to EPA, they remain applicable to this consultation. They are as follows:

- * Attachment 1 is entitled "National Marine Fisheries Service Consultation Initiation Checklist". This is a generic checklist NOAA Fisheries developed to assist Federal agencies in meeting the information requirements necessary to initiate consultation. Other Federal agencies have found this outline valuable for organizing and submitting information. The checklist itemizes the types of information needed for all consultations, including the project background/history, description of the action and the action area, status of the species and their critical habitat, environmental baseline in the action area, effects of the action on listed species, cumulative effects, and conclusion. The checklist includes the identification of the type and severity of direct and indirect effects of the action (p. 3, section V).
- * Attachment 2 is entitled "Pesticides and Pacific salmon: technical guidance for NOAA Fisheries section 7 pesticide consultations" (10/1/02). This document, which has been prepared by NOAA Fisheries, provides internal technical guidance to NOAA Fisheries in conducting section 7 consultations involving the effects of pesticides on listed salmonids and their habitats. The goal of this document is to ensure a consistent scientific approach when evaluating the effects of pesticides. It is designed to complement and be consistent with EPA risk assessment guidelines, as reflected in EPA's *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998). This document should in part assist EPA in understanding how NOAA Fisheries intends to evaluate the potential impacts of pesticides on listed salmonids and their habitats. We would appreciate it if all future consultation requests on pesticide registrations follow this guidance to the maximum extent possible.
- * Attachment 3 is entitled "Steps of Consultation Using Diazinon as an Example." This flow diagram illustrates the integration of ecological risk assessment into the ESA section 7 consultation evaluation. This approach is described in detail in Attachment 4 which includes general and specific comments for the diazinon initiation package.

Finally, we note that the initiation request letters do not mention consultation under the Magnuson-Stevens Fishery Conservation and Management Act (MSA) (§305(b)(2)) and its implementing regulations (50 C.F.R. 600 Subpart K). Federal agencies are required to consult with NOAA Fisheries regarding actions that are authorized, funded, or undertaken by that agency that may adversely affect Essential Fish Habitat (EFH). Please indicate whether EPA intends to consult under the MSA on these registration actions.

Please contact Steven Landino at 360-743-6054 if you have any questions.

DRAFT - DO NOT DISTRIBUTE OR QUOTE

May 23, 2003

Sincerely,

D. Robert Lohn
Regional Administrator

enclosures

cc: Michael Horton, USFWS
Ken Seeley, USFWS
Maria Borogia, USFWS
Don Steffeck, USFWS

May 23, 2003

bcc: Michael Crouse, HCD
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John Stein, NWFSC
Nat Scholz, NWFSC
Tracy Collier, NWFSC

Attachment 4:
General and Specific Comments for Diazinon Initiation Package

Overview of the Consultation Process

To provide context for the comments and requests for information that will follow, we offer the following summary of the process we plan to follow during this consultation and the analyses we will conduct (either together or separately). To facilitate more effective communication between our agencies during this consultation, we have made an effort to summarize the consultation process using terms and procedures contained in EPA's *Guidelines for Risk Assessment* (U.S. EPA 1998).

The first step of our assessment process requires our agencies to clearly identify the action that we will consider in this consultation. For example, we will need to determine if this consultation will encompass the effects of re-registering products containing the active ingredient diazinon (as compared with the various formulations that contain the active ingredient, as well as degradates, mixtures, surfactants, adjuvants and inert (other) ingredients), the uses of those products, or some combination of the two.

EPA's initiation package seeks consultation on the diazinon active ingredients. Diazinon formulations occur, at a minimum, as a wettable powder or in a granular form. Please supplement the initiation package by identifying, to the maximum extent possible, all of the chemical ingredients in each formulated product. Additionally, please provide and analyze all available information that examines the toxicity of inert ingredients, adjuvants, and surfactants, when used in combination with the active ingredient.

NOAA Fisheries next must identify the action area for this consultation, as defined in 50 C.F.R. § 402.02. NOAA Fisheries will work with EPA to identify the direct and indirect effects of the proposed action on the environment, which will require us to consider the fate and transport of the active ingredient diazinon, its degradates, and metabolites (or the broader components of the formulated products), and their effects on the ecology of the landscapes and watersheds in which they would occur. For example, this would include effects on the trophic ecology or the physical structure — submerged or floating aquatic vegetation — of aquatic ecosystems receiving concentrations of this insecticide or degradates like diazoxon, which can be a more effective cholinesterase inhibitor than diazinon. NOAA Fisheries will also consider the effects of any activities that may be interrelated or interdependent with this action. These analyses will help ensure that we identify an action area for this consultation that encompasses all relevant effects.

The third step of our analyses will evaluate the available evidence to determine the likelihood of listed species or critical habitat ("listed resources") being exposed to various environmental concentrations of the active ingredient diazinon, its degradates, or metabolites (or the broader components of the formulated products), which includes estimating the intensity, duration, and frequency of exposure. These analyses will assume that the potential direct effects of the re-registration of diazinon on listed resources will be a function of the intensity (measured in terms of estimated environmental concentrations), duration, and frequency of the exposure (although we recognize that some biologically significant effects are likely to result from low levels of exposure). Our exposure analyses will also try to estimate (a) the species, populations, and life stages that would be exposed to the direct and indirect effects of active ingredient diazinon, its degradates, or metabolites (or the broader components of the formulated products); (b) the conditions of that exposure (in space and over time); (c) the portions of critical habitat that would

be exposed, including any constituent elements; and (d) the conditions of that exposure.

Although computer simulations can support the analyses we must conduct in section 7 consultations, our effects analyses must consider the actual circumstances species face in their natural environments. As a result, to complete our exposure analyses, EPA will need to help us make inferences about the probable behavior of diazinon, its degradates, and metabolites (or the broader components of the formulated products) in real space and time based on the results of the various models EPA uses for its fate and effects analyses.

For listed resources that are likely to be exposed to the active ingredient diazinon, its degradates, or metabolites (or the broader components of the formulated products), the fourth step of our analyses will evaluate the available evidence to identify the probable acute or chronic responses, which would include death or injury; trophic effects; and behavioral responses that would have longer-term, chronic effects on the viability of populations of species. For example, this step of our analyses will try to develop and examine "stressor-response" relationships (relationships between various acute and chronic endpoints and estimated environmental concentrations of compounds) to characterize the probable responses of listed resources to exposure to the active ingredient diazinon, its degradates, or metabolites (or the broader components of the formulated products).

The fifth step of our analyses will combine the information on exposure with the information on responses to estimate the risk the active ingredient diazinon, its degradates, or metabolites (or the broader components of the formulated products) pose to listed resources. Our risk analyses will begin with the species, populations, and life stages that would be exposed, combined with information on their probable responses upon exposure. As part of this step, we will examine the information available on each species' status, the impact of activities that we include in the environmental baseline for the consultation, and cumulative effects. To support any inferences we might make about these various effects on listed species, we plan to use demographic models to estimate the probable consequences on the species' likelihood of surviving and recovering in the wild (estimated using measures such as probability of persistence over 20, 50, or 100 years or median time to extinction derived from cumulative distribution functions).

Consultation regulations state that "The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat" (50 C.F.R. 402.14(d)). In the context of pesticide effects, NOAA Fisheries believes that the best available science includes the primary, peer-reviewed scientific literature. It also includes the "grey literature" such as agency technical reports and data submitted to the EPA by pesticide producers during the registration process.

EPA's effect determinations are based on exposure and toxicity information for these chemicals that is contained in the Registration Eligibility Decisions (REDs). In evaluating pesticides for re-registration, the EPA evaluates the studies submitted by the pesticide producers as the basis for the Agency's risk assessment. The RED does not necessarily consider the peer-reviewed (or open) scientific literature or other sources of information regarding the potential toxicity of a pesticide to salmonids or other non-target aquatic organisms. Also, the RED does not contain data from studies published after the document was developed.

For a risk determination in the context of the ESA, NOAA Fisheries believes that the RED does not by itself constitute the best available scientific and commercial data. An initiation package/

biological assessment must consider the peer-reviewed scientific literature and other relevant sources of technical information. Please clearly indicate all sources of data that were used in EPA's effects determinations.

General Comments on EPA's Risk Assessment Approach and the Initiation Package

According to EPA's internal *Guidelines for Ecological Risk Assessment* (Federal Register 63(93):26846-26924, May 14, 1998), the first phase of an ecological risk assessment is the formulation of the problem. This provides the foundation for the entire assessment. The problem formulation phase involves the selection of assessment endpoints, or explicit expressions of the actual environmental value that is to be protected. Assessment endpoints are operationally defined by an ecological entity and its attributes. The EPA Hazard Evaluation Division Standard Evaluation Procedure Ecological Risk Assessment guidance (June 1986) does not address the topic of problem formulation. In addition, the document identifies a suite of generic tests for use in ecological risk assessment. It does not allow for variation based on species specificity or targeted effects.

In the context of the ESA, the ecological entities are threatened or endangered salmonids and their habitat, and the assessment endpoints are the essential biological requirements of salmon and steelhead and their prey base. Thus, salmonid essential biological requirements are critical environmental values to be protected. To be consistent with EPA's (1998) internal guidelines, assessment endpoints need to be explicitly defined before a risk assessment proceeds. If they are not defined, or if assessment endpoints are vague, the subsequent stages of a risk assessment will be compromised.

The "endangered species risk assessment" documents submitted by EPA do not clearly define the essential biological requirements of salmonids. Although the diazinon risk assessment states that direct effects result from exposure to a pesticide at levels that may cause "harm," EPA did not appear to define "harm" using the ESA regulatory definition of the term (50 C.F.R. § 222.102). Please clarify how "harm" was defined in this step of EPA's risk assessment.

The effects determination submitted by EPA does not adequately define the scientific basis for using the "standard endangered species criterion of the Risk Quotient exceeding 0.05". A pesticide may have multiple modes of action (or toxicity), hence, justification is needed for using LC₅₀ data as the sole means of determining toxicity, to the exclusion of essential physiological and behavioral systems of salmonids. Please provide the applicable definitions and justifications.

We will also need to examine approaches to "error" as they relate to interpreting the results of statistical analyses and any decision-making process we have to develop and apply during this consultation. Although we recognize the high degree of uncertainty that will accompany many of the analyses in this consultation, NOAA Fisheries is concerned that the ecological risk assessment may be biased toward concluding that a pesticide does not pose an ecological risk to listed resources, when in fact, it does (a "Type II error"). The lack of information on chronic sublethal effects, or effects posed by degradates, mixtures, surfactants, adjuvants and inert (other) ingredients, can very quickly lead to the conclusions of false negatives (concluding that an effect does not pose an ecological risk to listed resources when, in fact, it does) or Type II errors. Type II errors for listed resources are very significant in a section 7 analysis as NOAA Fisheries must assure that these errors are minimized.

The data in the initiation package for diazinon originated primarily from the IRED, written in

July 2002. For example, in the case of use information, the data in the IRED were derived from nationwide information. As a result, neither the maps nor the information on usage, such as pounds of product applied, can be readily translated to the location of this consultation. The ESA consultation should be conducted on a specific spatial and temporal scale. Region-specific information should be provided, and if not available, it should be estimated to the greatest extent possible, based on best available information. Please provide information on the sources of diazinon, where it is applied, the concentrations at the sources, the application patterns (frequency and intervals), its transport, degradation/attenuation, and persistence by watershed within each ESU. All of this information will be factored into the exposure analysis to develop exposure profiles for listed resources.

Potential conservation measures have been identified in the section in the initiation package that compares the ESUs and diazinon use areas. Those potential conservation measures include buffers to minimize runoff and drift into surface waters, and/or restriction of application to the ground. Other than working with the Washington State Department of Agriculture to develop applicable protective measures for Washington State, how, when, where, with whom and what does EPA propose to implement potential conservation measures? Conservation measures are factored into the scope of the action and as such are analyzed for their ability to avoid, minimize or mitigate jeopardy or adverse modification of critical habitat or take.

General Comments Related to the Description of the Action

Description of the action. From the materials EPA has provided, we could not be certain whether the scope of this consultation is limited to the re-registration of the active ingredient diazinon, the various formulations that include this active ingredient, the uses of the active ingredient (or the various formulations), or some combination of these options. We have discussed the answers to these questions several times when we have met, but we need to document those discussions as a final description of the action so that we can ensure that the scope of this consultation is commensurate with the scope of the action.

We will also need to know the duration of the re-registration to ensure that our effects analyses project far enough into the future. For example, the transmittal letter suggests that EPA is considering changing the registration of diazinon (i.e., cancellation of granular formulations, deletion of aerial applications, strong recommendations to reduce orchard dormant spray, cancellation of a number of crops, eliminated foliar application to leafy vegetables, and phase-out all residential uses by December 2004). Does the scope of this consultation include the current registration, the proposed changes, or both? Depending on the answer to this question, please provide clearer descriptions of the current registration conditions and the proposed registration changes. In addition, please describe what will happen after December 2004; that is, whether all residential uses of the product will cease, whether some uses will continue in limited situations, or whether the product will continue to be used until all existing supplies are exhausted. If some residential uses will continue after December 2004, please provide any estimate of how long the product is expected to remain in use. Similar questions will need to be addressed for the agricultural cancellations or phase outs. Each of these questions has important consequences for the scope of our effects analyses.

To help us understand EPA's authorities, programs, and the nomenclature associated with both, please provide the citations to the statutory authority for the action under consultation and the purpose of the action. For example, will the scope of this consultation only cover EPA's determinations pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (7

U.S.C. 136a, FIFRA) or will the scope of this consultation also include authorities under sections 18 and 24 of the FIFRA?

General Comments Related to the Action Area

As you know, the delineation of action areas is a critical step in any consultation because the action area determines which listed resources we will consider in a consultation, and determines the information we include in an Environmental Baseline and cumulative effects evaluation for a consultation. Based on the information you provided to initiate consultation, we will need further discussions to delineate an action area for our consultation on diazinon.

Specifically, the information you provided only refers to the 26 threatened or endangered species of Pacific salmon, without describing the specific area that may be affected by the proposed re-registration of diazinon. At this level of resolution, the action area encompasses any state in which the pesticide is registered for use, even if there are no uses in particular drainage basins in that state. We will need to try to describe the action area on a finer scale to make the analyses we have to conduct more meaningful.

Please clarify the following:

- * Please provide greater geographical clarity as to EPA's view of the action area.
- * It appears that the requests for consultation pertain solely to the effects on salmonids. Please explain your rationale for excluding other listed marine species that may be within the action area, and when EPA intends to consider the potential effects of pesticides on these other species.

General Comments Related to Exposure Analyses

By regulation, our consultations have to consider the effects of three classes of activities on listed resources: (1) the projected effects in the action area of continuation of environmental baseline conditions, including federal activities that have undergone section 7 consultation; (2) the effects of the action in the action area, including direct and indirect effects and the effects of interrelated and interdependent activities; and (3) the effects of future State, local, and private activities that are reasonably certain to occur in the action area; and (4) the effects of natural phenomena and human activities on the range-wide status of the listed species or the value of designated critical habitat. In short, NOAA Fisheries must consider the effects of the action on listed resources in light of the other major activities that may alter the species' status or the condition of its designated critical habitat.

NOAA Fisheries considers how these activities co-occur with listed resources in different landscapes over time, along with any particular circumstances associated with that co-occurrence (which we call "exposure analyses"). NOAA Fisheries is responsible for assembling the information on the status of the listed resources and the environmental baseline, but we will need to work cooperatively during the consultation to identify probable exposure scenarios that would result from the proposed re-registration of diazinon. At least initially, we will need to consider the various sources of the compound and any waters that may be affected as the compound, its degradates, and metabolites (or the broader components of the formulated products) flow downstream from those sources. That will require us to consider degradation scenarios that combine transport and downstream attenuation with physical degradation rates, or we may have

to assume maximum exposures throughout the action area.

Further, we will need to develop exposure scenarios based on mixtures and multiple stressors. From the standpoint of multiple stressors, the potential exists for a pesticide to cause additive, or synergistic toxicity when it co-occurs with other registered pesticides. As is evident from recent U.S. Geological Survey National Water Quality Assessment (NAWQA) studies in several western basins, pesticides frequently enter salmonid habitat as mixtures. The labels themselves generally allow mixing. This raises the possibility of multiple effects resulting solely from pesticide mixtures.

Multiple toxicities can have antagonistic, additive, or synergistic effects on organisms. For example, if diazinon and a second pesticide have a common mechanism of toxicity, the potential for additive effects in the environment should be evaluated if the second pesticide is also expected to occur in salmon or steelhead habitat. For example, S. Anderson, as part of an EPA grant (National Center for Environmental Research, grant # R826603) looking at the "Genetic Diversity in California Native Fish Exposed to Pesticides" has detected diazinon, as well as other pesticides, in the study sites' water. That study identified a genotoxic effect of induction of DNA strand breaks correlated with the onset of the pesticide pulse.

Accordingly, please provide and analyze all available information that addresses potential or known multiple exposures that can occur by the interaction of pesticides that are the subject of this consultation with other pesticides that are currently registered and in use. We assume that EPA possesses some information bearing upon the topic of multiple exposures of pesticides, since under the Food Quality Protection Act of 1996, EPA must assess the cumulative effects to human health of pesticides and other chemicals that demonstrate a common mechanism of toxicity.

Finally, EPA is responsible for providing the initial cumulative effects analyses to comply with our regulations (50 C.F.R. 402.14(c)), which encompass the effects of future State, local, or private actions that are reasonably certain to occur in the action area. The cumulative effects analysis should evaluate the likely effects on listed resources of future non-Federal activities in the action area that are reasonably certain to occur. This includes, but is not limited to, the use of pesticides other than the ones being evaluated, and how they interact with the pesticide under consultation. This requires, in turn, consideration of baseline environmental conditions in salmonid habitat (current state of relevant habitat conditions such as streamflow, temperature and other physical, chemical and biological attributes). Salmonids are exposed to many stressors other than pesticides, and this may affect their sensitivity to exposure to specific pesticides.

General Comments Related to Response Analyses

NOAA Fisheries will consider both acute effects associated with mortality, and chronic effects that have consequences for (1) the species' reproduction, numbers, or distribution and (2) the conservation value of critical habitat that has been designated for these species. As a result, mortality is not the only assessment endpoint that will be relevant to our analyses; we will consider chronic, sublethal assessment endpoints and try to establish relationships between those endpoints and estimated environmental concentrations of diazinon, its degradates, and metabolites.

These chronic, sublethal endpoints would include (but not be limited to), the quantity and quality of the prey base of the various species; distribution and abundance of floating or submerged

vegetation that provides cover for juvenile stages of the various salmon species; reproductive behavior, reproductive success; migratory patterns, rates of growth in individuals, the population dynamics of competitors and predators for the various salmon species, and multiple effects on listed resources that are caused by the interaction of pesticides that are the subject of this consultation with other pesticides that are currently registered and in use. All of these analyses may require us to make inferences from best available data.

General comments on the Interim RED for Diazinon

The cover letter states that EPA will not finalize the decisions on registration until the cumulative risks for all of the organophosphates are considered. Cumulative risk information for all organophosphates is critical to the assessment of direct and indirect effects from exposure to mixtures both from the tank and in the environment. What is the schedule for completing that evaluation? What is the framework for that evaluation? What are the opportunities for incorporating an evaluation of sublethal effects beyond the standard mortality and reproduction endpoints in the cumulative risk analysis? What are the opportunities for expanding the ecological risk assessment for diazinon to incorporate peer-reviewed literature and ecological risk elements from EPA's agency-wide guidance document (1998)? While EPA may not be able to incorporate additional sublethal endpoints from the peer-reviewed literature and elsewhere to revise the ecological risk assessment on diazinon at this time, NOAA Fisheries must use best available information to estimate the cumulative risks. In doing so, our findings could differ significantly from EPA's cumulative risk and ecological risk assessments.

Questions from the Interim RED

1. p. 7. C. Use Profile. There is a continuing use for the control of plague infected fleas on squirrels in CA. Where is this a problem and how is the insecticide applied for this public health exemption?
2. p. 8. Methods and Rates of Application. Does this section reflect the current and future changes in application methods given the restrictions and phase outs?
3. p. 14. III. A. 2. Dietary risk from drinking water. This section states that the half life of diazinon is significantly longer in waters of neutral and alkaline pH than in waters of acidic pH. Some of the waters in California are of neutral or slightly alkaline pH during the dry season. The San Joaquin river system in particular has been known to remain at high pH levels (as high as pH 9 sometimes) for weeks. How was the pH factor examined for effects in the ecological effects section? Were elevated pH scenarios examined? Diazoxon, a toxic degradate, was not found in laboratory studies, but was found in field dissipation studies. Please provide more details of the differences between the studies, such as water temperature or pH that may have lead to this finding. Please reference these studies.
4. p. 14. a. Surface water. What is the level of quantification referred to in the sentence "For example, diazinon was detected frequently (35% of NAWQA samples) at concentrations ranging from below the level of quantification up to 3.8 ppb."
5. p. 27. B. 2. EECs. Table 8. All of the exposure scenarios listed in Table 8 have apparently been eliminated in the recent diazinon actions. The scenarios should be reexamined and new EECs generated based upon the allowable rates and application methods.

The use of aerial applications has been eliminated. How do the assumptions for drift change in response to this? For orchard crops, how will dormant sprays be applied?

6. p. 30. 3. C. Toxicity to plants. This section states that plant testing is required for diazinon because of its use pattern. Has this testing been done yet? If so, please share the results. If not, when is it expected to be completed? In table 14, what are the measurement units for the aquatic plant results?

7. p. 32. 4. C. Risk to Aquatic Species. These are good summary sections. Please note that the overall health of the aquatic ecosystems, at least in California, is generally poor due to water diversions and human-caused alterations to the river systems.

P. 32, second and third paragraphs. The risk quotient ranges for acute and chronic freshwater invertebrates are presented. How were those ranges derived and where are they displayed in this document? Similarly, the chronic risk quotient range for freshwater fish is presented. How was this range derived and where is it displayed in the document? Please provide those ranges if they are not contained in this document.

8. p. 36. first paragraph. A number of sublethal effects in salmon, such as lethargy when undisturbed, abnormal forward extension of the pectoral fins, darkened areas on the posterior part of the body, when startled, sudden rapid swimming in circles followed by severe muscular contractions, reduced reproduction rates, malformed fry and lowered cholinesterase levels, have been exhibited. Where are those findings cited? Were those anecdotal findings or could they be incorporated in the ecological risk assessment? Please provide copies of the studies that documented the above-listed effects. It is possible that the above findings could be expected to lead to increased predation of salmon.

9. p. 36. third paragraph. Has spray drift been linked to aquatic contamination?

10. p. 37. fourth paragraph. The document states that if all changes outlined in the IRED are incorporated into the labels, all current risks will be acceptably mitigated. Please discuss how the proposed changes will mitigate all current risks. Are the proposed changes intended to mitigate risks to threatened and endangered species?

11. p. 43. IV. C. Regulatory position. When did the 5 year period for phase out of granular formulations for use in lettuce begin? What pests does it control? If liquid applications will continue to be used, has the new rate and application methodology been examined to determine an EEC or other exposure scenario? Is the rate reduction from 4 lbs a.i./ac to 1 lb a.i./ac granular diazinon immediate?

This statement says that foliar applications on all vegetable crops will be canceled. Elsewhere it says that the number of applications allowed in orchard use will generally be reduced to one per dormant season and one per in season. Please clarify which orchard crops use both in season and dormant season applications. Will foliar applications be used in those crops that have in-season uses (as seems to be the implication for almonds)? How many in-season and dormant applications were allowed before?

In California, many nurseries are container nurseries, meaning that the plants are being grown in the containers in which they are shipped to market. As such, it is not unusual for them to operate on cement pads with the containers elevated on pallets. This can lead to excessive runoff and

delivery into stormwater or stream systems. Was this scenario been examined in setting the reduced rates for ornamentals?

Can the agency require monitoring of pests before the dormant season application to determine if the application is needed? Can the agency require that the applications be planned around expected rains? It is not unusual in California to have significant time between storm events during the rainy season.

Does the statement, "... the Agency believes that it is reasonable to allow two years, . . . , to put these mitigation measures in place" mean that they are scheduled to be in place at the end of 2004? If not, when does the two-year period start and end?

12. p. 48. 5. Spray Drift Management. Please describe or provide information on operation methods for ground boom and airblast application systems. Has the use of buffers been examined with these systems (e.g. do not apply along the outer row or X feet from water)?

Questions from the Environmental Risk Assessment

1. p. 38. Information on urban use of diazinon is limited. Water quality sampling in urban areas shows diazinon to be present in 75% of the samples and mixtures of other pesticides to be present in more than 10% of samples. Please elaborate and provide data and citations from urban stream samples to more clearly illustrate the potential pesticide loads in streams due to urban pesticide use.

Specific Comments on the Initiation Package

1. Introduction. Problem Formulation. EPA's *Guidelines for Ecological Risk Assessment* (1998) describes that the problem formulation step in ecological risk assessment provides the foundation for the entire process by refining the objectives of the exercise. As discussed above, this step should be incorporated into the ecological risk assessment for diazinon, and the assessment should be rerun.

2. p. 4, fourth paragraph. The second sentence states that very many of the inerts are in "exceedingly small amounts". This statement is questionable, as the labels for the diazinon products list inert ingredients ranging from 52-86%. If product formulation testing is driven by the amount of inert ingredient in the product, and if EPA does not consider inert ingredient in concentrations greater than 50% to warrant testing, then there could be a significant oversight in which formulations get tested. **[I don't understand this last sentence.]**

The last sentence speaks to a "sufficient quantity" of inert ingredients in the product to warrant concern and having OPP attempt to evaluate the potential effects. As mentioned above, there is a concern about what constitutes "sufficient quantity" if 52-86% is considered to be an "exceedingly small amount". How can that disparity be eliminated? In addition, are there any sequence steps or criteria to determine how formulated products get "black box" tested or receive structure-activity analysis?

3. p. 4, last paragraph. Has formula specific toxicity testing been conducted for diazinon? If so please advise us of the results. Specifically, what fish toxicity tests have conducted on formulated products?

4. p. 4. The GENEEC model was developed in 1995, well after diazinon was registered. Has diazinon been reevaluated using the newer models GENEEC and PRZM-EXAMS? If so, please present and discuss the assumptions underlying the models. Have the assumptions been verified with any monitoring? Did the re-examination result in any changes in the EECs? These questions are not meant to comment on the use of this methodology; NOAA Fisheries is interested in the supporting information behind EPA's determination.
5. p. 5. second paragraph. Given NOAA Fisheries' concern about the potential effect of inert ingredients, the lack of toxicity data from formulated products is a great concern. How can this program be revised to enhance this information which is critical for the response and risk analyses of the consultation?
6. p. 7. The IRED states that plant testing is required for diazinon. Please incorporate that information into this section and determine if this paragraph is still appropriate.
7. p. 8. Please clarify the statement "As a result, and excepting those very persistent pesticides, we would not expect that pesticidal modification of the food and cover aspects of critical habitat would be adverse beyond the year of application." What about when the pesticide is applied every year or throughout the year, as seems to be the case with diazinon? Please note that salmonid streams may be missing a year's run which could be reestablished by strays. The absence of salmonids in a particular year should not be assumed into the future.
8. p. 9, second paragraph and Table 2. The Hazard Evaluation Division Standard Evaluation Procedure (June 1986) does not describe the risk quotient approach. Please provide more background for this approach and describe how the risk quotients were derived. It would be very helpful to provide an example using the diazinon product.
9. p. 11. first full paragraph. The initiation package states that the research by Scholz et al (2000) contradicts the 6x safety factor hypothesis and concludes that the 6x hypothesis needs to be re-evaluated relative to olfaction. When is EPA planning to conduct this re-evaluation? If the re-evaluation has already been conducted, please provide the results.
10. p. 14. first paragraph. The document identifies rates of diazinon use per application and per year and states that California is one of the states with significant usage. Is the usage in California greater than that cited for agricultural and non-agricultural sites? What is that usage for California? What is the usage for the other states which fall within the boundaries of the 26 ESUs?
11. p. 14. fourth paragraph. It is acknowledged that the USGS map does not take into account the use changes resulting from the reregistration process. If EPA is requesting consultation on the future cancellation and phase out, a map of the action area should be provided that represents the use changes following reregistration. The map should capture the changes in the action area for the 26 ESUs.
12. p. 17. first paragraph. Are the data on survival and growth of parental fathead minnows included in Table 4? What is the basis for the assumption that the LOEC of 3.2ppb for hatchability of fathead minnows is not much above the NOEC? Are those studies discussed on page 17 or illustrated on Table 4 all of the best available science? If the data are not included in this initiation package, please provide them.

13. p. 26. Incidents. Please provide more information regarding the incidents involving the labeled use of diazinon. What were the circumstances under which the incidents occurred? What were the ages/stages of the fish that were killed? What were the measured diazinon water concentrations?

14. p. 26. EECs from models. Are any of the other modeled scenarios, besides almonds, appropriate for California? The document states that the EEC scenarios presented are largely unrealistic for Pacific salmonids. Please update these scenarios for the consultation or explain how exposures are being determined for this biological evaluation. As described above, since this section 7 consultation is covering 26 ESUs of salmon and steelhead, modeled scenarios for cropping patterns in Washington, Oregon, and Idaho should be included (exposure in space and over time).

This section also mentions the California Endangered Species bulletins. Has any monitoring been done to determine if this voluntary approach is being implemented and having any benefits?

15. p. 27. Table 11. How were the 60-day chronic EECs derived as they do not correspond with the values in Table 32d of the Ecological Risk Assessment? Are either the chronic EEC or chronic risk quotient based on the Scholz et al (2000) values?

16. p. 28. Please discuss the certified applicator system and how it is monitored or has been evaluated to determine its effectiveness.

P. 28, second paragraph. Basing the analysis of the future use of diazinon on past sampling and past modeling is acknowledged to be difficult. However, as described above, if EPA is requesting consultation on the future uses, the models should be re-run to develop future EECs for both residential and agricultural use based on the pending labeling changes and cancellations.

17. p. 30 g. B. Invertebrates. Please note that NOAA Fisheries does not necessarily agree with the determination that the macroinvertebrate density, rather than the specific types of macroinvertebrates present, is the important factor in determining forage quality for salmonids. EPA should check with salmonid dietary experts to determine if all macroinvertebrates are of equal value for rearing salmonids, or if the variety and timing of the species is important.

18. p. 31. C. Criteria. Have the effects of environmental mixtures of pesticides been considered during the development of any of the water quality guidelines/criteria identified in this section? Please provide those data.

19. p. 32. It is stated that most of the California County Agricultural Commissioners require that the pesticide county bulletins are followed. How do they require this? Are they monitored in any manner?

P. 32, first paragraph. Can EPA extrapolate on future use of diazinon from trends in usage of other pesticides that have had similar restrictions or cancellations? There should be some way to estimate or infer the spatial and temporal extent of agricultural use. Given the almost complete ban on residential use, the best case could be estimated and qualified with information on trends of actual use following other cancellations.

20. p. 32. second paragraph. EPA suggests that further analysis of existing monitoring data from California be conducted to determine whether and how the county bulletins are providing

protection. How does EPA propose that that analysis be conducted?

21. p. 33. There is considerable data presented for California. Has it been screened to exclude those areas which do not support salmonids? For example, Imperial county in the south-east corner of California produces much of the winter vegetables for the region but this area drains to the Colorado River and the Sea of Cortez, which are not salmonid waters. They also experience different pest pressures and thus must use different pesticides in different application strategies than other parts of the state. Was the use of pesticides in this area screened out in the tables?

Are the effects determinations made on the basis of the existing rates of use and application methodologies? Were the proposed changes evaluated already?

22. p. 32. What sources were used for the acres of particular crops planted in each county for the states of Oregon, Washington, and Idaho? In order to conduct a credible exposure analysis, additional information should be provided. To the extent that it is possible, the diazinon application locations, the formulation concentrations, the application patterns (frequency, interval), and the transport/degradation/attenuation/persistence of the chemical should be correlated by watershed within each ESU. That will provide spatial and temporal exposure information that will be applied as exposure profiles in the risk analysis for each species and critical habitat.

23. p. 33. Table 13. Why was 10 pounds or more chosen as a cut-off? Crops with less than 10 pounds of diazinon should be included to determine both drop off as well as continued use. Use, even if it is low, may take place in locations with significant populations of threatened and endangered species, potentially causing exposure risks, and should be included in this analysis.

References

Scholz, N.T., Truelove, N.K., French, B.L., Berejikian, B.J., Quinn, T.P., Casillas, E., and T.K. Collier. 2000. Diazinon disrupts antipredator and homing behaviors in chinook salmon (*Oncorhynchus tshawytscha*). Can. J. Fish. Aquat. Sci. 57:1911-1918.

U.S. Environmental Protection Agency. 1998. Guidelines for Ecological Risk Assessment. Federal Register 63(93):26846-26924.

Attachment 3: EPA Pesticide Consultation - Steps of Consultation (March 20, 2003)

Memo to the file: Strategy for searching the peer-reviewed scientific literature for studies relating to the pesticide diazinon and threatened or endangered species of Pacific salmon

Report by: Rachel Friedman

Date begun: 6/10/03

Date Completed: 2/13/04

Rationale

This document describes a database search strategy that was used to identify the peer-reviewed scientific literature specific to pesticides and threatened or endangered species of Pacific salmon. The peer-reviewed literature is an essential component of the technical or scientific information that collectively constitutes the "best available scientific and commercial data" [50 CFR 402.14(d)] used during section 7 consultations under the Endangered Species Act. While the peer-reviewed literature is not the only source of scientific information to be considered (other sources include grey literature, agency reports, government studies, books, and other printed materials), it is the most widely accepted source of critically reviewed scientific studies that are readily available to the section 7 consultation process.

This search strategy identifies several on-line scientific databases as well as keywords to identify studies relating to 1) the chemistry, application, fate, and transport of pesticides (i.e., exposure), and 2) the toxicological effects of pesticides on salmonids and aquatic or estuarine habitats (i.e., biological response). Search results are incorporated into EndNote, a standard bibliographic software program, and screened individually for relevance to salmon and steelhead. In addition to EndNote, a separate notebook is used to log each search, including the dates, databases, and keywords used.

Scenario

The U.S. Environmental Protection Agency, Office of Pesticide Programs has initiated section 7 consultation on the registration and use of the organophosphate insecticide diazinon. Consultation will be conducted across 26 Evolutionarily Significant Units (ESUs) of Pacific salmon and steelhead. The action area will, at a minimum, include the ESUs within California, Oregon, Washington and Idaho. The registration is based on the risk assessments for diazinon. EPA's risk assessments were derived from acute and chronic sublethal effects levels (Table 1), as well as from the estimated exposure concentration (EECs) derived from modeling (Table 2) (EPA 2002).

Table 1. Diazinon Estimated Environmental Concentration (EEC) ranges.

Number of Diazinon Applications	Peak EEC (parts per billion (ppb))	21-day Average EEC (ppb)	60-day Average EEC (ppb)
1 - 5	8.89 - 429	7.94 - 356	6.39 - 258

Table 2. Acute and Chronic Toxicity of Diazinon to Fish.

Toxicity Measure	Fish species	Toxicity Level
LC ₅₀ ¹ (ppb)	Rainbow Trout	90.0
NOEC ² (parts per million) (ppm)	Brook Trout	<0.55
LOEC ³ (ppm)	Brook Trout	<0.55

1. LC₅₀ – Lethal concentration that is estimated to kill 50% of a test population.
2. NOEC – No-observed effect concentration or the highest concentration in which there is no significant difference between the chronic/sublethal test and the control treatment.
3. LOEC – Lowest-observed effect concentration or the lowest concentration in which there is a significant difference between the chronic/sublethal test and the control treatment.

Questions

1. Do the best scientific and commercial data available support the EECs?
2. Do the best scientific and commercial data available support the acute and chronic sublethal effects levels?
3. What mechanisms influence the fate and transport of diazinon?
4. Given the various life history strategies and life history stages that could be exposed to diazinon, how would Pacific salmon and steelhead be expected to respond to ecologically relevant concentrations?
5. What best scientific and commercial data are available regarding the fate and transport and effects of mixtures of diazinon and other pesticides?

Databases

Databases used in this literature search were accessed via the Internet. They included ASFA (Aquatic Sciences and Fisheries Abstracts), BIOSIS, TOXLINE, Web of Science, Current Contents, and the EPA's ECOTOX database. All databases were accessed via online connections through the NWFSC library (lib.nwfsc.noaa.gov) except ECOTOX, which was accessed via the EPA's own website (www.epa.gov/ecotox). These represent the most current and frequently used databases for identifying peer-reviewed ecotoxicological studies. Collectively, these databases contained very recent articles as well as studies dating back to 1975. Although sources of information were almost exclusively peer-reviewed journal articles, some government reports and conference proceedings were also identified.

Keywords

Databases were queried using a wide array of keywords specific to ecological exposure and toxicological response. Individual keywords (i.e., *diazinon*) were used individually and in combination or pairing of key words (i.e., *diazinon* and *salmon*). Pesticide-specific keywords included the CAS number, common name(s), trade names, degradates, active ingredient, inert ingredients, adjuvants, and surfactants. For example, diazinon keywords included *diazinon*, 333-41-5, *diazoxon*, *basudin*, *dazzle*, *gardentox*, *kayazol*, *knox out*, *nucidol* and *spectracide*. Salmon-specific keywords included *alevin*, *Atlantic salmon*, *bull trout*, *char*, *chinook*, *chum*, *coho*, *cutthroat trout*, *fish*, *fry*, *Oncorhynchus mykiss*, *O. tshawytscha*, *O. kisutch*, *O. nerka*, *O. gorbuscha*, *O. clarkii*, *parr*, *pink*, *rainbow trout*, *salmonid*, *smolt*, *sockeye*, and *steelhead*. Habitat-specific keywords included *algae*, *amphipod*, *aquatic insects*, *aquatic invertebrates*, *assemblage*, *benthos*, *chironomid*, *Chironimidae*, *Chlorella*, *cladoceran*, *copepod*, *Copepoda*, *Daphnia*, *diatom*, *Diptera*, *Ephemeroptera*, *Gammaridae*, *IBI*, *index of biotic integrity*, *infauna*, *macrocosm*, *mayfly*, *mesocosm*, *microcosm*, *mysid*, *Neoptera*, *periphyton*, *Plecoptera*, *Selenastrum*, *Simuliidae*, *stonefly*, *Trichoptera*, and *zooplankton*. Exposure-specific keywords included *abiotic degradation*, *accumulation*, *adsorption*, *advection*, *bioaccumulation*, *bioavailability*, *bioconcentration*, *biotransformation*, *biotic degradation*, *body burden*, *clearance*, *degradates*, *degradation*, *deposition*, *depuration*, *dispersivity*, *dissolved*, *distribution*, *drift*, *elimination*, *elimination rate*, *environmental fate*, *environmental exposure*, *environmental concentrations*, *estuary*, *evaporation*, *exposure assessment*, *exposure pathway*, *exposure profile*, *exposure routes*, *fate*, *flood irrigation*, *fog*, *fugacity*, *ground water*, *hydrograph*, *hydrologic cycle*, *mass loading*, *mass transport*, *matrix*, *metabolism*, *metabolites*, *mobility*, *modeling*, *monitoring*, *organic carbon*, *P450*, *photodegradation*, *rain*, *risk assessment*, *rivers*, *runoff*, *sediment*, *sorption*, *spray*, *stability*, *streams*, *surface water*, *transport*, *trophic transfer*, *uptake*, *use*, *volatilization*, and *wind*.

Search Results

A bibliography of results for diazinon (876 total records) was created. The bibliography of peer-reviewed literature was developed according to the procedures outlined above. The search was conducted over approximately a 6 week period of database searching and building the Endnote library. Three Endnote libraries have been built: Diazinon-fish - contains 380 references pertaining to effects to fish (includes the ECOTOX references),

Diazinon-fatetrans-filtered - contains 496 references pertaining to fate and transport,

ECOTOX database 1-27-04 - contains 81 references pertaining to effects to fish.

Managing Search Results

The entire set of results (or hits) from each on-line database search was transferred to End Note. After all databases were queried, the records from the individual files were imported into two EndNote files (diazinon-fish and diazinon-fatetrans-filtered), and the duplicate entries were deleted. This resulted in two files containing all retrieved records. In addition, a third file was created from an ECOTOX database search. As ECOTOX only contains data on fish effects, those references were

added to the diazinon-fish file and the duplicates were deleted. An electronic backup of the bibliography was stored on a remote computer, and paper copies were printed and stored on file.

Initial Screen for Data Relevance

After the EndNote files were created for the pesticide, individual records were screened for data relevance. Studies in a language other than English, studies that did not pertain to riparian, aquatic, or estuarine organisms (i.e., human health/occupational exposure, mammals, pesticides other than diazinon), and incomplete records (no listed author, year, or record type) were deleted from the EndNote files. For the diazinon search, the remaining articles were retrieved from the NWFSC library, the University of Washington libraries, on-line journals, and through interlibrary loan. Electronic versions (pdf files) were also obtained where available.

Rejected studies have been kept, marked with a short written statement of why they were not relevant to the initial screen, and put into a separate file (electronic and paper).

References

U.S. Environmental Protection Agency. 2002. Interim Reregistration Eligibility Decision for Diazinon, Case No. 0238. Office of Prevention, Pesticides and Toxic Substances. Washington, D.C.